

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

(Filed: September 16, 2014)

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| * * * * *           | * <b>PUBLISHED</b>                          |
| LISA BRAY,          | *   |
|                     | * No. 10-207V                               |
| Petitioner,         | *   |
|                     | * Special Master Dorsey                     |
| v.                  | *   |
|                     | * Fact Ruling; Sufficiency of Evidence;     |
| SECRETARY OF HEALTH | * Receipt of Vaccination; Influenza (“flu”) |
| AND HUMAN SERVICES, | * Vaccine; Guillain-Barré Syndrome (“GBS”)  |
|                     | *   |
| Respondent.         | *   |
| * * * * *           | *   |

Franklin John Caldwell, Jr., Maglio, Christopher & Toale, Sarasota, FL, for petitioner.  
Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

### **RULING REGARDING FINDINGS OF FACT<sup>1</sup>**

#### **I. Introduction**

On April 7, 2010, Lisa Bray (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program<sup>2</sup> (“the Program”) in which she alleges that she received a trivalent influenza (“flu”) vaccination on December 2, 2008, which caused her to

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<sup>1</sup> Because this ruling contains a reasoned explanation for the special master’s action in this case, the special master intends to post it on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). All decisions and substantive rulings of the special masters will be made available to the public unless they contain trade secret or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to redact such information before the document’s disclosure. Absent a timely motion, the decision shall be made available to the public in its entirety. Upon the filing of a timely motion to redact, along with a proposed redacted version of the decision, if the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from the ruling made available to the public. 42 U.S.C. § 300aa-12(d)(4); Vaccine Rule 18(b).

<sup>2</sup> The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

suffer Guillain-Barré Syndrome (“GBS”). See Petition (“Pet.”) at 1. Because petitioner’s medical records do not document the administration of a flu vaccine, a fact hearing was held to address the issue of whether petitioner received the flu vaccination. Pre-Hearing Order, May 16, 2014 at 1.

Upon consideration of the record as a whole, the undersigned finds that a preponderance of the evidence supports a finding that petitioner received an influenza vaccination prior to the onset of her GBS.

## **II. Procedural Background**

The case was initially assigned to Chief Special Master Gary J. Golkiewicz on April 7, 2010. Petitioner filed medical records on April 26, 2010, followed by her affidavit and a Statement of Completion on September 10, 2010. Respondent submitted her Rule 4(c) Report on November 9, 2010, noting that petitioner’s medical records did not document the administration of a flu vaccine as alleged. Respondent’s Rule 4 Report (“Resp’t’s Rep’t”), November 9, 2010 at 15; Pet. Ex. 2, at 12. At a status conference on January 4, 2011, petitioner stated that she intended to file an expert report to support her petition. Order, January 4, 2011 at 1. After several motions for extensions of time, petitioner filed the expert report of Thomas F. Morgan, M.D. on January 3, 2012.

The case was reassigned to Special Master Laura Millman on May 9, 2012. Petitioner filed a supplemental expert report on June 13, 2012. After Special Master Millman expressed concern about whether petitioner had presented sufficient evidence to prove that she received the flu vaccine, petitioner submitted an additional supplemental expert report on December 10, 2012.

The case was reassigned to the undersigned on January 14, 2013, and petitioner filed a third supplemental expert report on February 11, 2013. The undersigned ordered petitioner to obtain additional medical records regarding the administration of the flu vaccine, which petitioner filed on June 24, 2013, and November 25, 2013. Petitioner also filed the affidavit of petitioner’s husband, Mr. Steven Bray, on February 10, 2014. On May 16, 2014, the Court scheduled a fact hearing to determine whether petitioner received the flu vaccination. Pre-Hearing Order, dated May 16, 2014, at 1.

A fact hearing was held on July 10, 2014, before the undersigned. Transcript (“Tr.”) at 1. Petitioner and her husband, Mr. Steven Bray, testified at the hearing. See Tr. at 2. After the hearing, the undersigned ordered petitioner to file documents referenced during the hearing, including a Vaccine Adverse Event Reporting System report (“VAERS”) report, which had not been previously filed. Order, dated July 18, 2014. The documents were filed on September 9, 2014, as Exhibits 34 through 37. The matter is now ripe for adjudication.

## **III. Summary of the Evidence**

The undersigned has considered the entirety of the record, § 300aa-13(a)(1). See Paterek v. Sec’y of Health & Human Servs., 527 Fed. App’x 875, 884 (Fed. Cir. 2013); see also Veryzer v. Sec’y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are

bound by both § 300aa-13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”). The evidence presented includes: (1) petitioner’s medical records, (2) petitioner’s affidavit and testimony, (3) Mr. Bray’s affidavit and testimony, (4) a letter from petitioner’s nurse, and (5) a VAERS report. These sources of evidence are discussed below.

#### **A. Petitioner’s medical records**

On December 2, 2008, petitioner presented to her primary care provider, Sharon McLaughlin, R.N.C., at the Charlestown Health Care Center for a routine blood pressure check. Petitioner alleges that she received a flu vaccine at this visit, but there is no documentation of that vaccination in petitioner’s medical record. Pet. Ex. 2 at 24; Pet. at 1. Four days later, on December 6, 2008, petitioner visited her chiropractor at McGee Chiropractic complaining of pain and stiffness in her neck and back. Pet. Ex 6 at 11. Petitioner continued to complain of back pain and abdominal pain during a visit with Nurse McLaughlin on February 4, 2009. Pet. Ex. 2 at 21. On February 10, 2009, petitioner was admitted to Massachusetts General Hospital (MGH) and diagnosed with mild pancreatitis. Pet. Ex. 5 at 10. On February 13, 2009, petitioner returned to MGH complaining of back pain, parasthesias in her teeth, hands, flank, and thighs, diplopia, numbness in her hands and feet, and difficulty walking. Pet. Ex. 2 at 108, 109; Pet. Ex. 5 at 145. A lumbar puncture revealed elevated protein level and white blood cell counts. Id. Petitioner was diagnosed with the Miller Fisher variant of GBS. Pet. Ex. 5 at 11.

While hospitalized at MGH for GBS, a nursing progress note authored by Karoline Grogan, R.N., dated February 19, 2009, states that an influenza vaccine was ordered for petitioner, but that “patient already received this season.” Pet’r’s Ex. 7 at 330. Nurse Grogan also documented the order for the influenza vaccine in the medication record, and documented that the vaccination was not administered because the patient has “already received” it. Pet’r’s Ex. 7 at 377.

Over the next several months, petitioner’s condition slowly improved. Pet. Ex. 1 at 2-4, 10. During a monthly blood pressure check with Nurse McLaughlin on September 14, 2009, petitioner refused a flu shot, stating that she believed her flu shot in December 2008 caused her to develop GBS. Pet Ex. 2 at 13.

Petitioner’s medical records also include a note dated October 15, 2009, by Mary A. Ungaro-Dulaney, R.N. confirming that she had received a telephone inquiry from the Centers for Disease Control and Prevention (CDC) requesting information about petitioner’s treatment after her flu vaccination in December 2008. Pet. Ex. 2 at 11.

#### **B. Petitioner’s affidavit and testimony**

In her affidavit, petitioner stated that she received the flu vaccine on December 2, 2008. Pet. Ex. 8 at 1. She then described the decline of her health. Id. at 1-2. Petitioner explained that she first noticed numbness and tingling in her hands and feet in mid-December. Id. at 1. She experienced back aches, numbness, and tingling in her hands throughout January 2009. Id. Her pain was bearable until February 3, 2009, when she experienced severe pains in her abdomen and back with numbness in her face and teeth. Id. After being treated and discharged from

MGH, petitioner was transferred to Spaulding Rehabilitation Hospital (SRH) where she underwent physical, occupational, and speech therapy for over a month. Id. at 2.

At the fact hearing on July 10, 2014, petitioner testified that she regularly received flu shots every year up through 2008 due to the frequent traveling and training required for her job, which often exposed her to illness. Tr. at 10. Petitioner testified that she and her husband discussed petitioner's flu shot each year—including 2008. Id. at 11. Petitioner further testified that after December 2, 2008, she was offered and refused a flu shot twice while hospitalized at MGH in February 2009. Id. at 14, 29. She told her treating nurses on both occasions that she had already received the flu shot in December 2008. Id. at 29. Petitioner again refused a flu vaccination on September 14, 2009, after informing Nurse McLaughlin that she had learned that the flu vaccine could cause GBS. Id. at 13.

### **C. Mr. Steven Bray's affidavit and testimony**

Petitioner's husband, Mr. Steven Bray, testified in his affidavit that petitioner "was in the habit of getting a flu shot every year given that her bank job took her to branches in many locations." Pet. Ex. 34 at 1. He recalled that petitioner had gotten a flu shot in 2008 and began experiencing numbness and tingling in her hands and feet in December 2008. Id. At the fact hearing, Mr. Bray confirmed petitioner's testimony that he and petitioner discussed her flu shot each year. Tr. at 7.

### **D. Nurse Sharon McLaughlin's letter**

On October 6, 2009, Nurse McLaughlin wrote a letter detailing her recollection of petitioner's December 2, 2008 visit. Pet. Ex. 2 at 12. While Nurse McLaughlin did not clearly remember giving petitioner the vaccine, she stated that she believed petitioner received a flu shot on December 2, 2008. Id. Nurse McLaughlin concluded that petitioner's medical records do not document the flu shot because she forgot to record it. Id.

### **E. VAERS Report**

A VAERS report was completed by Nurse McLaughlin on October 6, 2009, the same day that she authored the letter referenced above. Nurse McLaughlin documented that she administered the vaccine but she did not document the date of vaccination. Pet. Ex. 36 at 1. The lot number for the vaccine and date of adverse event (January 31, 2009) were documented. Id. Nurse McLaughlin documented petitioner's adverse event as "Guillain-Barre Syndrome." Id.

## **IV. Applicable Legal Standards**

Under the Vaccine Act, petitioner must first prove by a preponderance of the evidence that she "received a vaccine set forth in the Vaccine Injury Table." § 300aa-11(c)(1)(A). The preponderance of the evidence standard means a fact is more likely than not. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010).

Although contemporaneous documentation of vaccination from a health care provider is the best evidence, its production is not an absolute requirement. See Centmehaiey v. Sec’y of Health & Human Servs., 32 Fed. Cl. 612, 621 (1995) (“The lack of contemporaneous, documentary proof of a vaccination . . . does not necessarily bar recovery.”). Thus, special masters have found in favor of vaccine administration where contemporaneous documentation of vaccination is unavailable as long as other forms of evidence have provided preponderant evidence of vaccination administration. For example, corroborative, though retrospective, medical notations have been found to provide preponderant evidence of vaccine administration. See Wonish v. Sec’y of Health & Human Servs., No. 90-667V, 1991 WL 83959, at \*4 (Cl. Ct. Spec. Mstr. May 6, 1991); Groht v. Sec’y of Health & Human Servs., No. 00-287V, 2006 WL 3342222, at \*2 (Fed. Cl. Spec. Mstr. Oct. 30, 2006) (finding a treating physician’s note “4/30/97-Hep B. inj. # 1 (not given here) ([patient] wanted this to be charted)” to be sufficient proof of vaccination); Lamberti v. Sec’y of Health & Human Servs., No. 99-507V, 2007 WL 1772058, at \*7 (Fed. Cl. Spec. Mstr. May, 31, 2007) (finding multiple medical record references to vaccine receipt to constitute preponderant evidence of administration).

Testimony alone has also been found to provide preponderant evidence of vaccine administration. Alger v. Sec’y of Health & Human Servs., No. 89-31V, 1990 WL 293408, at \*7 (Cl. Ct. Spec. Mstr. Mar. 14, 1990). In Alger, the special master found the oral testimony alone “more than adequate to support a finding that the vaccine was administered to [petitioner].” Id. at \*7.

## **V. Evaluation of the Evidence**

Ample documentation corroborates petitioner’s testimony that she received a flu vaccination on December 2, 2008. First, Nurse McLaughlin concluded that she gave petitioner the vaccination after admitting that she must have forgotten to record it. Pet. Ex. 2, at 12. The fact that petitioner’s medical records do not document several of her other annual flu vaccinations supports Nurse McLaughlin’s conclusion that she could have forgotten to record the 2008 vaccination as well.

Further, in February 2009, Nurse Grogan at MGH recorded that petitioner reported that she had already received the seasonal flu vaccine. Pet. Ex. 7 at 330; 377; Tr. at 14. Petitioner’s recollection that she had received the flu shot in December when Nurse Grogan inquired about it two months later provides additional support that petitioner was vaccinated in December 2008.

Later that year, on September 14, 2009, petitioner advised Nurse McLaughlin that she did not wish to receive another flu shot. Pet. Ex. 2 at 13. She stated her concern that the previous flu shot from December 2008 had caused her to suffer GBS. Id. Petitioner’s consistent statements from February to September regarding the administration and date of her flu shot corroborates Nurse McLaughlin’s belief that she gave petitioner the flu shot in December 2008.

Moreover, Nurse McLaughlin completed a VAERS report, in which she documented that she administered the vaccine, and there was a follow-up request from the CDC on October 15, 2009, regarding the hospital in which petitioner was treated after experiencing side effects from the flu shot. These documents also support petitioner’s claim. Pet. Ex. 2 at 11; Pet. Ex. 36 at 1.

Finally, petitioner and her husband gave consistent testimony in their affidavits and during the fact hearing that petitioner received the flu vaccine each year, and again on December 2, 2008.

Accordingly, the undersigned finds that petitioner received a flu vaccination on December 2, 2008.

## **VI. Conclusion**

The undersigned finds that petitioner has provided preponderant evidence that she received a flu vaccine prior to the onset of her GBS. The respondent is ORDERED to file a status report in the 30 days stating how she would like to proceed.

Any questions regarding this Ruling may be directed to my law clerk, Francina Segbefia at (202) 357-6385 or at Francina\_Segbefia@ao.uscourts.gov.

**IT IS SO ORDERED.**

s/Nora Beth Dorsey  
Nora Beth Dorsey  
Special Master